UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 18-10568-RGS

DUSA PHARMACEUTICALS, INC.

v.

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG

MEMORANDUM AND ORDER ON
BIOFRONTERA'S MOTION TO EXCLUDE
THE OPINIONS OF DR. ROBERT ZAMENHOF

October 9, 2020

STEARNS, D.J.

Biofrontera moves under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude two facets of the testimony of DUSA's expert witness, Dr. Robert Zamenhof: (1) his testing of the BF-RhodoLED leading him to conclude that its "measured output over an active emitting area is at least 60% of the measured maximum over all operation distances"; and (2) his opinions regarding non-infringing alternatives under the second of the *Panduit* factors.[1]

[1] The *Panduit* factors, so named for *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978), is "[o]ne 'useful, but non-exclusive' method to establish the patentee's entitlement to lost profits." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir.

In *Daubert*, the Supreme Court abandoned the general acceptance test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), finding it superseded by the more liberal relevancy test of Fed. R. Evid. 702.[2] *Daubert*, 509 U.S. at 586-587. *Daubert* imposes a duty on federal trial judges to play the role of a "gatekeep[er]," *id.* at 597, insuring that the fact-finding process does not become distorted by "expertise that is *fausse* and science that is junky,"

2017). Under the *Panduit* test, a patentee is entitled to lost profits if it demonstrates:

> (1) demand for the patented product;
>
> (2) absence of acceptable non-infringing alternatives;
>
> (3) manufacturing and marketing capability to exploit the demand; and
>
> (4) the amount of profit it would have made.

Id. at 1285, citing *Panduit*, 575 F.2d at 1156.

[2] Under Rule 702,

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 159 (1999) (Scalia, J., concurring). Two gateposts frame the exercise of a judge's discretion to admit or exclude expert testimony. First, the witness must be shown to be sufficiently qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Second, the judge "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but [also] reliable" (and helpful to the finder of fact). *Daubert*, 509 U.S. at 589.

Daubert, as stressed in the advisory note to the December 1, 2000 amendment to Fed. R. Evid. 702, "did not work a 'seachange over federal evidence law,' and 'the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system.'" *Cf. United States v. Mitchell*, 365 F.3d 215, 245 (3d Cir. 2004) (Becker, J.) ("[T]he court is *only* a gatekeeper, and a gatekeeper alone does not protect the castle . . . .").

> *Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. . . . In short, *Daubert* neither requires nor empowers trial courts to determine which of several competing theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.

Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998) (citations omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the

traditional and appropriate means of attacking shaky, but admissible evidence." *Daubert,* 509 U.S. at 596.

With respect to his infringement analysis, Biofrontera questions Dr. Zamenhof's qualifications, claiming that he lacks sufficient experience in PDT. Biofrontera also challenges the reliability of his testing method, arguing that he excluded the edges of the BF-RhodoLED's light surface from his test area, and then limited his measurements to ten points in two arrays along the central axis. More forcefully, Biofrontera contends that Dr. Zamenhof's rationale for testing only the interior portions of the BF-RhodoLED – because that is the area of uniform light output – is circular and resulted-oriented, designed to achieve a conclusion of infringement.

Under the second of the *Panduit* factors, products lacking the advantages of the patented invention are not considered acceptable non-infringing alternatives for customers who choose the patented invention because of its advantages. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991) ("[I]f purchasers are motivated to purchase because of particular features available only from the patented product, products without such features – even if otherwise competing in the marketplace – would not be acceptable noninfringing substitutes."). According to Biofrontera, because Dr. Zamenhof is unfamiliar

with the PDT market and has no evidence of what motivates doctors in the decision to purchase PDT products, his opinion – that non-PDT products and non-FDA-approved illuminators do not constitute acceptable non-infringing alternatives – is unreliable and therefore ultimately unhelpful to the trier of fact.

In response, DUSA maintains, and the court agrees, that Dr. Zamenhof has the appropriate qualifications to opine on matters involving PDT testing and infringement. *See Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 80 (1st Cir. 2004) ("Rule 702 is not so wooden as to demand an intimate level of familiarity with every component of a transaction or device as a prerequisite to offering expert testimony. When, as in this case, an expert is 'qualified . . . by knowledge, skill, experience, training, or education,' Fed. R. Evid. 702, he need not have had first-hand dealings with the precise type of event that is at issue.") (citation omitted). Dr. Zamenhof has 40 years of experience in the field of medical physics with a focus on radiotherapy, and he has worked extensively in both academic and hospital environments. Like PTD, radiotherapy uses energy to activate chemicals for treating patients applying the identical principles of physics applicable in the world of PTD. In addition, Dr. Zamenhof spent three years developing and publishing a PTD protocol for treating patients. That the bulk of Dr.

Zamenhof's experience is not with PTD goes to the weight, and not the admissibility, of his opinions.

As for the design of his testing method, DUSA points out that the parties did not seek a construction for the claim term "active emitting area," and that Biofrontera's implicit reading – that the active emitting area covers the entire surface of the illuminator, finds no support in the patent. Rather, the patents' specification excludes the low output area of the illuminator from the "active emitting area." *See* '289 patent, col. 6, ll. 16-20 ("To avoid uniformity problems, one embodiment of the present invention utilizes a plurality of U-shaped tubes . . . . This arrangement allows the cathodes and their low output area to be located outside the active emitting area (effectively behind the patient's ears)."). In Dr. Zamenhof's report, what Biofrontera characterizes as the "effective treatment area" of the BF-RhodoLED – a 6 by 16 cm inner area of the 8 by 18 cm illuminator surface – constitutes the claimed "active emitting area." Dr. Zamenhof's understanding of "active emitting area" is not unreasonable and whether the accused BF-RhodoLED meets this claim element is a matter to be left to the factfinder.

As for the specific output sampling areas, DUSA notes that Biofrontera does not identify any industry standards from which Dr. Zamenhof deviated.

DUSA also notes that Biofrontera itself employs a similar light sampling method – measuring at 8 specific points along the central axis of the BF-RhodoLED – in reporting its light uniformity data to the FDA. The service handbook for the BF-RhodoLED also describes the same method for calibrating the light output of the device. Dr. Zamenhof's sampling method is sufficiently reliable to be presented to the factfinder.

The court also agrees with DUSA that based on his experience with similar technologies, Dr. Zamenhof is qualified to opine on the differences between the patented illuminator and other non-PTD treatments, as well as the relative advantages of the patented illuminator. Based on his work in hospitals and with doctors (although he is not himself a medical practitioner), he is qualified to give opinions as to a doctor's general preference to perform medical procedures having the imprimatur of FDA approval, and for shorter and non-invasive treatments over longer and invasive alternatives. That Dr. Zemenhof by his own admission has no hands-on familiarity with the PTD market, again, goes to the weight, and not the admissibility, of his opinions.

ORDER

For the foregoing reasons, Biofrontera's motion to exclude the opinions of Dr. Robert Zamenhof is DENIED.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE